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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,559	03/07/2002	Yasushi Ochiai	4367-0101P	9100

2292 7590 05/19/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Appli ation No.

10/091,559

Applicant(s)

OCHIAI ET AL.

Examiner

Rachel M. Bennett

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-- Th MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5&6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The examiner acknowledges receipt of IDS filed 6/17/02 and 12/26/02.

Information Disclosure Statement

1. The examiner acknowledges receipt of the information disclosure statements (IDS) submitted on 6/17/02 and 12/26/02. Accordingly, the examiner has considered the information disclosure statements.

Specification

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierre et al. (US 5300318).

Applicants claim a method of manufacturing a drug granule, comprising a granulation step of spraying a solution of a water soluble drug on a crystal of said water soluble drug.

Pierre discloses alimentary and/or medicinal active principles intended for feeding or treating ruminants are polished by spraying a solution of one or more active principles, resins and/or sugars onto the said active principles. The polished active principles are then coated with a polymer providing protection in the rumen. See abstract. It is preferred to employ a solution of sprayed onto a lysine and/or methionine granulate. The base granulate which is subjected to the polishing operation may be made from lysine hydrochloride crystals. The active principle is

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generally an amino acid such as methionine, lysine or one of its salts, phenylalanin, histidine, arginine, or tyrosine, a medicament such as a vitamin, antibiotic, or antiparasitic agent, or a protein. The diluents and fillers may be sugars, cellulose and/or silica. The granulate is screened so as to retain a granulate distribution between 200 and 4000 μm and preferably between 500 and 2500 μm . The coating contains at least one component which is chosen from basic polymers, copolymers, or mixtures. See cols. 1 and 2. The coating mixture solution is sprayed onto the polished granulate using a fluidized bed or any other spraying apparatus. The granulate obtained after coating exhibits increased stability. See col. 3 and claims 1-17. The reference is silent with regards to the granular strength.

While the reference is silent regarding granular strength, differences in granular strength will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such granular strength is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The reference teaches a drug granule, comprising a granulation step of spraying a solution of a water soluble drug on a crystal of said water soluble drug and further coating said drug granule with a release control film coating agent. Therefore, absent unexpected results, it would be obvious to one of ordinary skill in the art to optimize the granular strength because Pierre desires a stable granulate.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
May 12, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600